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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STUART, COLIN W

ART UNIT

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3771

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,058	Applicant(s) GRUNDLER ET AL.	
	Examiner COLIN STUART	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to an amendment filed 3/31/09. As directed by the amendment, claims 1-10 have been cancelled and claims 11-20 have been added.

Response to Arguments

2. In regards to the applicant's argument that "the pump in the Smith patent only moves fluid into the gas while the drive device of the present invention moves the fluid through the gas" on pg. 6 para. 2, the argument is not well taken because Smith states that "larger drops which may form within the chamber fall to its base and return to the reservoir via the conduit 17" (col. 5 ln. 12-14) therefore the fluid does move through the gas and the drive means is a circulating drive means in the sense that it circulates the fluid from the reservoir to the chamber and back to the reservoir.

In regards to the applicant's argument that "the controlled heater device does not heat the fluid but, instead, heats the gas/nebulized fluid mixture" and the statement that "it is very difficult to heat a gas in a proper way in order to avoid overheating the gas" on pg. 6 para. 4, the arguments are moot due to new grounds of rejection discussed below.

In regards to the applicant's argument that "there is no aerosol or droplets formed within the pressurized gas" on pg. 7 para. 5, the argument is not well taken because there is no limitations within the claims directed towards this argument.

In regards to the applicant's arguments: "it is not possible to reheat the flow of the humidified gas to the desired temperature in the relatively short tube 8" (pg. 8 para. 1), "the energy that is used to evaporate any fluid into gas is taken from the gas" (pg. 8

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para. 2) and "in the Hitzler patent, there is no heating of the fluid" (pg. 8 para. 3), the arguments are moot due to new grounds of rejection discussed below.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The circulating drive means disclosed in the specification appears to lack antecedent basis.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant asserts that the claim element "a circulating driving means" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, it is unclear whether the claim element is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph, because the claim language does not follow the "means for" followed by a functional limitation. If applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant is required to:

(a) Amend the claim to include the phrase “means for” or “step for” in accordance with these guidelines: the phrase “means for” or “step for” must be modified by functional language and the phrase must **not** be modified by sufficient structure, material, or acts for performing the claimed function; or

(b) Show that the claim limitation is written as a function to be performed and the claim does **not** recite sufficient structure, material, or acts for performing the claimed function which would preclude application of 35 U.S.C. 112, sixth paragraph. For more information, see MPEP § 2181.

In regards to claim 19, the language “the step of humidifying occurring before the step of controllably flowing the supplied gas” (lines 1-2) is unclear because the examiner cannot ascertain how the supplied gas can be humidified in the humidification chamber before being controllably flowing.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 11-15 and 18 rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,541,966).

In regards to claim 11, Smith shows a system for heating and humidifying a gas which includes a fluid reservoir 15, a humidification chamber 11 in fluid communication

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with the fluid reservoir and having a gas inlet 12 and gas outlet 13 (see Fig. 2). Smith's system also includes a circulating driving means in the form of "the gas pressure within the chamber 11 rises sharply and since the reservoir communicates with the chamber via conduit 17 this causes liquid to be forced up the tube 18... liquid emerges from the tip of the tube 18 and is entrained and nebulized by the rapidly moving gas flow" (col. 5 ln. 1-9). The circulating driving means, gas pressure, causes the water to flow through the gas flow in the humidification chamber and water "drops which may form within the chamber fall to its base and return to the reservoir via the conduit 17" (col. 5 ln. 12-14). Smith also includes "an electric heating element (not shown) such that the droplet size is minimized" (col. 5 ln. 14-16) which is cooperative with the circulating fluid of the fluid reservoir and elevates a temperature of the fluid which passes through the gas flow in the humidification chamber.

In regards to claim 12, Smith's system includes a sprinkler in the humidification chamber suitable for delivering the fluid into the chamber. The outlet of tube 18 (Fig. 2) is the sprinkler per its ordinary definition, to scatter in drops or particles, as it allows droplets of water to be "entrained and nebulized by the rapidly moving gas flow" (col. 5 ln. 8-9).

In regards to claim 13, Smith's system includes a surface 19 in the humidification chamber positioned to receive the fluid as "the water droplets impinge on the anvil 19" (col. 5 ln. 9-10).

In regards to claim 14, Smith's system includes a humidification chamber 11 which is pressurized as the "gas pressure within the chamber rises sharply" (col. 5 ln. 1-2) to circulate the fluid from reservoir and humidify the gas flow.

In regards to claim 15, the circulating driving means of Smith's system is a pumping means because as discussed above, the pressure acts on the fluid in the reservoir and pumps the fluid through fluid circuit 18 and to the humidification chamber 11 (see Fig. 2).

In regards to claim 18, Smith system uses a method for humidifying a gas which includes supplying gas from a reservoir, "inlet 1 which is connected in use to a compressed medical gas supply" (col. 4 ln. 6-7). The supplied gas is controllably flowing due to a "pressure regulating valve 2" (col. 4 ln. 10-11) and is heated and humidified by sprinkling the gas with a fluid flowing from reservoir 15 through the fluid circuit 18 (see Fig. 2). The now heated and humidified gas is then fed "into a suitable cannula (not shown) leading to the lungs of the patient" (col. 4 ln. 43-44).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitzler (4,829,781) in view of Thudor et al. (2003/0066526).

Note: the following is an alternative rejection of claim 11

In regards to claim 11, Hitzler shows a system for heating and humidifying a gas which includes a fluid reservoir 11, a humidification chamber 16 in fluid communication with the reservoir having a gas inlet 20 and outlet 25, and a circulating drive means 13 cooperative with the fluid reservoir and humidification chamber for passing a fluid from the reservoir through a gas and back to the reservoir (see Fig. 2). Hitzler is silent as to providing a heating means cooperative with the fluid of said reservoir for elevating a temperature of the fluid. However, Thudor teaches an apparatus for delivering humidified gas in which "the humidifier includes a heater base to heat the water chamber" (Thudor para 0060 ln. 1-2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hitzler's system to include the heater base as taught by Thudor in order to provide the out-flowing gas of the system at a more desirable temperature.

In regards to claim 16, the modified Hitzler's system includes a circulating driving means which is a rotation body 13 (see Hitzler Fig. 2 and col. 4 ln. 15-17).

In regards to claim 17, the modified Hitzler's system includes a circulating driving means in the form of a rotation body 13 which is a series of "rotating disks of the plate stack" (col. 1 ln. 21).

9. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (4,541,966) as applied to claim 18 above, and further in view of Brossman, Jr. (4,566,450).

In regards to claim 19, the humidification method of Smith's reference teaches all the limitations as discussed above, but does not specify performing the step of humidification before controllably flowing the supplied gas. However, Brossman teaches a humidification device which employs an inlet valve 9 on the conduit which controllably delivers the humidified gas to the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cannula of Smith's system to include an inlet valve for controllably delivering the flowing gas as taught by Brossman in order to ensure greater pressure control and that the pressure of the gas is suitable for delivery to a patient. By this modification the step of humidifying occurs before the step of controllably flowing the supplied gas.

In regards to claim 20, the modified Smith's reference includes the step of heating and humidifying in a chamber 11 which is pressurized as discussed above, and inherently has a temperature greater than a temperature of the gas fed to the patient as

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there will inherently be heat loss through the cannula which delivers the gas to the patient, the heat loss resulting in a decrease in temperature. The valve (9 Brossman) of the modified Smith's reference ensures the gas is depressurized to a level of normal respiratory gas.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Milewicz (6,010,118), Koch (6,102,037), and Ellsworth (5,524,848) are all related to a humidifier apparatus.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771